

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

09735619.121300

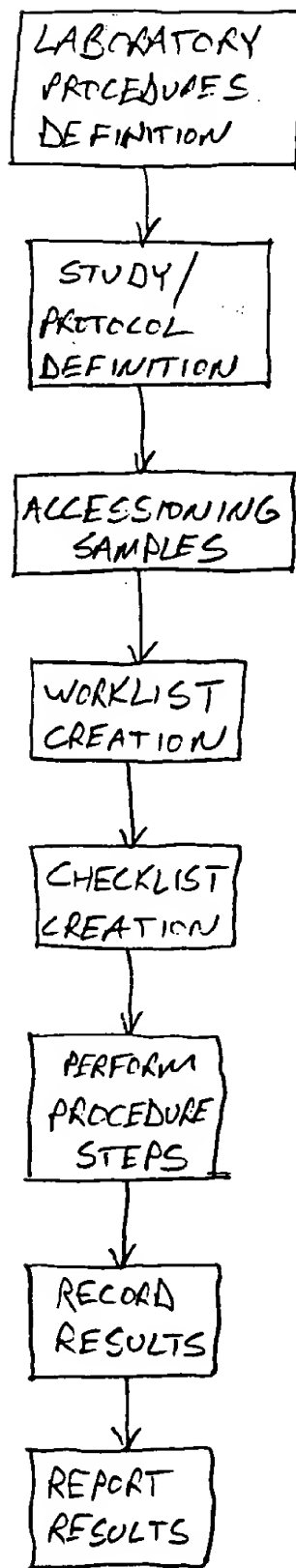


Fig 1

Study Setup

- Clinical Study Definition
- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

Study Protocol		Sponsor Study Number		Sponsor Company	
632-001		98005		A CO, JOHN DOE, Ph.D.	
98005		Sample test		B CO, JANE SMITH	
PS1		SS1		C CO, DAVID JONES	
Sponsor Protocol Title:		Pharmacokinetic Evaluation of Olanzapine (olanzapine chloride) and IR cypoflavin Administered Alone and in the Presence of Kaleconazole			
PPGx Protocol Title:		Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "F", and "G" alleles			
Procedures:		EOP Procedures		Subject Attributes:	
[HIA] Isolation, 3 mL whole blood, Purpure K2		SpectroMax DNA quantitation		Subject Number	
CYP2C9 3		CYP2C9 2Vci 7		Gender	
				Birthdate	
				Ethnicity	
Final Storage: Tube Range [1]		Cascade Accession Number		Barcode Length	
Investigator: JOHN DOE, Ph.D.		New		Save	
Study No. 632-001		Modify		Cancel	
Investigator: JOHN DOE, Ph.D.		Delete		Done	
Created: 10/4/99 12:02		Modified: 10/5/99 14:38		DNALIAS	
DNALIAS		DNALIAS		DNALIAS	

FIG. 2

Accessioning

Clinical Sample

Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Workflow

FIG. 3

FIG. 3

Sample Tracking

- Supports Multiple Container Classes
- Allows User Defined Container Geometries & Templates
- Maintains Sample & Container Location
- Permits Flexible Sample Loading & Rearrangement
- Tracks and Maintains Container & Sample Ownership

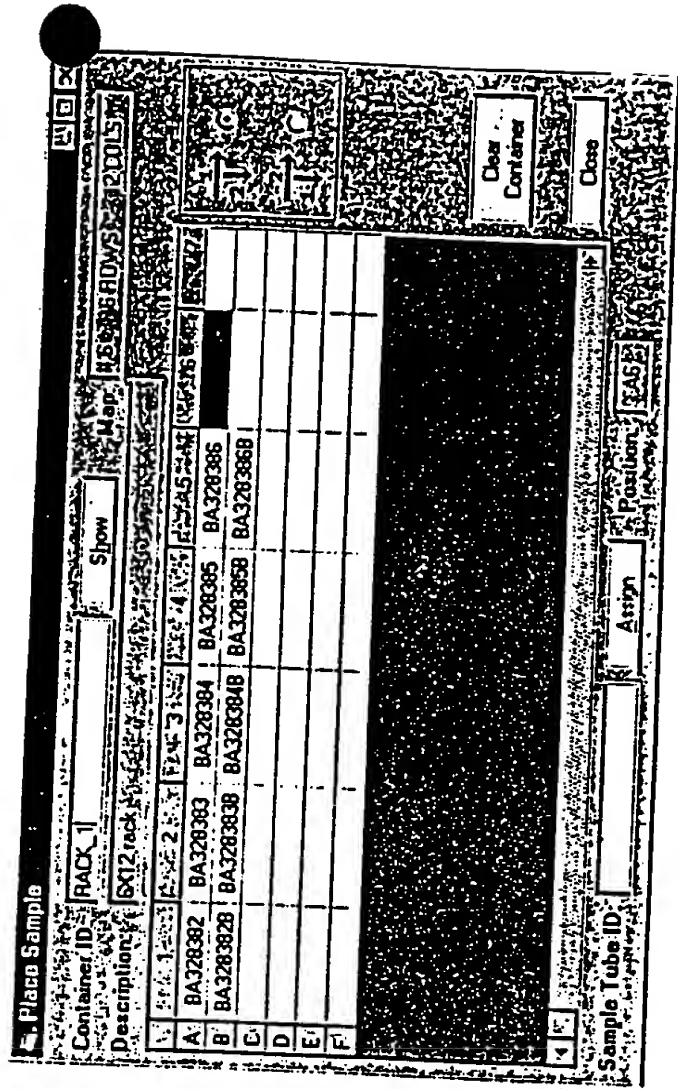


FIG. 4

Procedure		Status	SOP Number	SOP Version
DNA Isolation, 3 mL whole blood, Pargene Kit		APPROVED	GEN9709	C
2D6 Allele 'A' Identification		APPROVED	CYP2D6A	A
SpectroMax DNA quantitation		APPROVED	MAX9802	A
CYP2C9-3		APPROVED	CYP2C9-3	A
CYP2C9-2 Ver. 7		APPROVED	CYP2C9-2	A
CYP2C9-2 Ver. 6		APPROVED	CYP2C9-2	A
Procedure Name				
2D6 Allele 'A' Identification				
Procedure Description				
Laboratory Protocol for Identification of CYP2D6 'A' Allele by AFLP-PCR				
Gene		SOP Number		
CYP2D6		CYP2D6A		
Alleles		SOP Version		
A		A		
Status		APPROVED		
Created		New		
DNALIMS		Modify		
10/4/99 12:02		Delete		
Modified		Close		
DNALIMS		10/5/99 10:59		
Print		Save As		

FIG. 7

Procedure Steps

- A Single Step in a Lab Procedure
- Multiple Types:
 - Transfer
 - Dilution
 - Concentration Adjustment
 - Sample Preparation
- Highly Customizable
- Plug-in Architecture to Add New Types
- Interfaces to Automation

Procedure Steps

Procedures: DNA Isolation, 3 mL whole blood, Purogene Kit

Step	Step Input Type	Batch Input Type	Batch Functional Type	Batch Level
Thaw frozen blood	Check Box			Batch
Gently mix sample	Check Box			Batch
Transfer 3 mL of blood to Lysis tube	Functional		Transfer	Batch
Add 9 mL of RBC lysis to RBC lysis tube	Functional		Reagent Addition	Batch
Mix and incubate 10 minutes at room temperature	Check Box			Batch
Centrifuge 10 minutes at 3000 RPM	Text			Batch
Pour off supernatant into isothermally waste cont.	Check Box			Batch
Resuspend cell pellet by vortexing	Check Box			Batch
Add 3 mL of Cell Lysis Solution	Functional		Reagent Addition	Batch
Sample can be stored for 18 months at RT in Cell Lysis Solution	Text			Batch
STAMP PRINT	Text			Batch

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Type: ☒ Informational ☐ Check Box ☐ Sample ☐ Batch

Batch: ☒ Informational ☐ Check Box ☐ Sample ☐ Batch

Volume	To final volume	Reagent name	Reagent prefix	Volume optional	Wave scanning	Lock parameter
9000.231	FALSE	RBC Lysis S			TRUE	TRUE

Created: 10/5/99 09:00 Modified: 9/30/99 14:42

Buttons: New, Delete, Modify, Save, Cancel, Close, Save Sequence

FIG. 8

Genotype Results

- Accommodates Values for Multiple Genes, Alleles & Assays
- Provides Master Review by Accession Number
- Supports Acceptance & Final Approval by Study Director
- Imports Results Electronically or Manually

Study Protocol		Accession No.		Status
PS1	PS1	A3		OPEN
PS1	PS1	A4		OPEN
PS1	PS1	A5		OPEN
PS1	PS1	A6		OPEN
PS1	PS1	A7		OPEN
PS1	PS1	A8		OPEN
PS1	PS1	A9		OPEN

Accession No.		Status
AG		OPEN

Genotyping		DNA Purification		Chain Of Custody	
GENE	STATUS	INTERPRETATION	EXTENSIVE METABOLIZER	ENTERED BY	ENTERED ON
CYP2C9	COMPLETE			DNALIMS	10/6/99 6:48

Gene		Batch		Procedure		Created By		Created On	
m2	Batch	Batch	Batch	CYP2C9 Ver. 7	DNALIMS	10/6/99 6:09 48 PM	DNALIMS	10/6/99 6:09 48 PM	DNALIMS
m2	Batch	Batch	Batch	CYP2C9 Ver. 7	DNALIMS	10/6/99 6:09 48 PM	DNALIMS	10/6/99 6:09 48 PM	DNALIMS
FINAL RESULT									

FIG. 9

— Study

— Lab Procedures

— Sample

Results

Flexible Audit Reporting

Chain of Custody by Accession

FIG. 10

- | Sample # | Storage # | µg/ml | Protocol | Start Vol. | DNA Vol. | Yield | A260 | A280 | A280 | Subject Number | Initial | Date of Birth |
|----------|-----------|-------------|----------|------------|----------|-------|------|------|------|----------------|---------|---------------|
| EAI11111 | 0 | Sample test | 09/06/00 | 499 | 0 | 0 | 0 | 0 | 0 | 11kal | 5/31/66 | |
| EAI11112 | 0 | Sample test | 02/19/00 | 48 | 0 | 0 | 0 | 0 | 0 | 2 hbb | 8/2/67 | |
| EAI11113 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 0 | 0 | 3 lsc | 5/2/66 | |
| EAI11114 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 0 | 0 | 4 jmm | 4/11/74 | |
| EAI11115 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 0 | 0 | 5 lmr | 9/9/72 | |
| EAI11117 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 0 | 0 | 1 kpl | 5/31/66 | |
| EAI11116 | 0 | Sample test | 09/06/00 | 98 | 0 | 0 | 0 | 0 | 0 | 2 hbb | 8/2/67 | |
| EAI11118 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 0 | 0 | 3 lsc | 5/2/66 | |
| EAI11119 | 0 | Sample test | 09/06/00 | 582 | 0 | 0 | 0 | 0 | 0 | 4 jmm | 4/11/74 | |

FIG. 11